Guidelines for Oral Contraceptive Administration for Medical Officers



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Ministry of Health & Family Welfare
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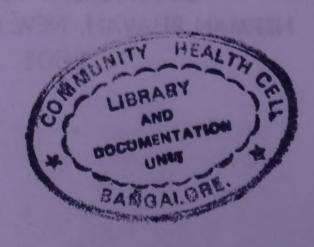
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GUIDELINES FOR ORAL CONTRACEPTIVE ADMINISTRATION FOR MEDICAL OFFICERS

Issued by
TECHNICAL OPERATIONS DIVISION
MINISTRY OF HEALTH AND FAMILY WELFARE
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ORAL CONTRACEPTIVE
ADMINISTRATION
FOR
MEDICAL OFFICERS



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Table of contents

Preface	5	
Acknowledgement		
Introduction to National Guidelines for Oral Contraceptive	9	
Administration for Medical Officers		
Section A: Combined oral contraceptive		
4	11	
1.1 Combined oral contraceptive		
1.2 Mechanism of action		
1.3 Effectiveness		
1.4 Advantages		
1.5 Disadvantages		
2. Counselling	17	
2.1 Counselling for family planning		
2.2 Method-specific counselling		
2.3 Counselling on return visit		
2.4 Counselling a client who wants to stop using COC		
3. Eligibility criteria for use of combined oral contraceptive	21	
3,1 Indications		
3.2 Precautions		
4. Client assessment	25	
4,1 History taking		
4.2 General and systemic examination		
4.3 Pelvic examination		
4.4 Laboratory Examination		
4.5 Record		
5. Guidelines for administration of combined oral contraceptive	27	
5.1 Steps for instructing a client		
5.2 Record		
5.3 Follow up schedule		
6. Management of side effects	31	
References		

Sec.	tion B	37
1.	Introduction to Centchroman	
1.1	Centchroman	
1.2	Mechanism of action	
1.3	Effectiveness	
1.4	Advantages	
1.5	Disadvantages	39
2	Counselling	
2.1	Counselling for family planning	
2.2	Method-specific counselling	
2.3	Counselling on return visit	
2.4	Counselling clients who want to stop using the Centchrome	42
3	Eligibility criteria for use of Centchroman	110000000000000000000000000000000000000
3.1	Indications	
3.2	Precautions	12
4.	Client assessment	43
4.1	History taking	
4.2	General and systemic examination	
4.3	Pelvic examination	
4.4	Laboratory examination	
4.5		illograpo)
5.	Guidelines for administration of Centchroman	44
5.1	Steps for instructing a client	
5.2	Record	
5.3	Follow up schedule	can mail
6.	Management of side effects	47
Re	ferences the second	
	Annexures	48
1 -	Drug interactions with COC	
2 -	Rumours	
3 -	Breast examination	
4 -	Pelvic examination	
5 -	Combined oral contraceptive screening and follow up card	
6 -	List of contributors to the guidelines	

PREFACE

One of the immediate objectives of the National Population Policy 2000 is to address the unmet needs of contraception. To achieve this objective, all efforts are being made to promote various contraceptive methods for spacing births among young couples, especially when the felt need for spacing among the younger age groups is increasing as evident from the National Family Health Survey II (1998-99).

The Guidelines on Oral Contraceptive Administration for Medical Officers are developed to provide quality services to the clients who need such services. Every effort has been made in preparing these guidelines to ensure that these are of practical value. I hope these guidelines for oral contraceptive administration for medical officers will be of use to the trainers as well as the trainees for promoting Oral Contraceptives as a spacing method in the National Family Welfare Programme.

(A.R. NANDA)

Secretary, Ministry of Health and Family Welfare (Department of Family Welfare)

Government of India

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I acknowledge the contribution of all the experts who have given their valuable time and labour to bring out this guideline (List of experts given in Annexure 5). I am indebted to Mrs. Meenakshi Datta Ghosh for her keen interest and encouragement. I am especially grateful to Dr. Saramma Thomas Mathai for revising the existing National Guidelines. Dr. Kalaivani's contributions in reviewing the documents is acknowledged. I would also like to acknowledge the support given by Dr. V.K. Behal, and the help rendered by Mr. Madhu Sudan, Mr. Venkataraman, and Mr. Kale, in typing. The illustrations used in the Guidelines have been adapted from the following publications.

WHO: Manual for the Provision of Intra Uterine Devices. R.H. Grey 1980. (Diagrams on pelvic examination)

[Dr.Lalrintluangi] Deputy Commissioner [RSS]

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Contraceptive Administration for Medical

Officers

The National Population Policy 2000 lists the review of Standards for clinical and non-clinical methods of contraception as one of the operational strategies. To operationalise this strategy, the existing National Guidelines for oral contraceptive administration for Medical Officers, developed in the early nineties, have been reviewed and revised by experts and a new section on Centchroman, the non-hormonal contraceptive has been added. The Guidelines provide the basic minimum standards to be followed for providing quality care while administering oral

The Guidelines include two sections.

Section A: Combined oral contraceptive

Section B: Centchroman

contraceptives.

Part A: Combined Oral Contraceptive

1. Introduction to combined oral contraceptive

At present about 100 million women worldwide and about 5.45 million women in India use oral contraceptive pills. In most countries, 'the pill' has been the most popular form of reversible contraceptive as it offers women an effective, safe and easy method of preventing pregnancies. The first Combined Oral Contraceptive (COC) introduced in 1960s contained high doses of synthetic hormones such as oestrogen and progestogen and had many side effects. The currently available COCs contain low doses of oestrogen and progestogen and have fewer serious side effects. Over the years, the COC is one of the most researched products. The health benefits of the COC outweigh the possible side effects and infrequent complications that occur in a small percentage of women. It is a contraceptive of choice for women who want to postpone first pregnancy by a reliable method.

The COCs have been part of the National Family Welfare Programme since early 1960. In spite of safety and high efficacy, the percentage of currently married women using 'the pill' is low. The National Family Health Survey (NFHS) II (1998-99) showed that only 2.1% of currently married women, aged 15-45 years, is using 'the pill'. The rumours and myths about 'the pill' and the side effects of 'the pill' are reported to be the two major reasons for such low usage. To promote the sustained use of the COC, it is important to counsel clients to clarify rumours and to provide reassurance/treatment in case of side effects. Selection of clients is another important factor in ensuring sustained use of the method. Considering the advantages of the method, it is important to improve the quality of care to increase the acceptability and continuation of the method especially when the felt need for spacing among the younger age group is increasing (NFHS II).

1.1 Combined oral contraceptive

Based on the results of several clinical trials conducted in India and elsewhere, the National Family Welfare Programme introduced the low dose COC in the eighties. The COC used in the National Family Welfare Programme contains:

Norgestrel 0.30 mg per tablet

Ethinyl Estradiol 0.03 mg per tablet

The COCs used in the National Family Welfare Programme are available under two brand names - Mala N under the free distribution scheme and Mala D under the social marketing programme (at a subsidised price). These are monophasic combination pills containing the same amount of oestrogen and progestogen in each pill. Each packet of Mala N and Mala D contains 21 contraceptive pills and 7 iron tablets. Other types of COCs are commercially available.

1.2 Mechanism of Action

COCs provide effective protection against pregnancy by:

- i. Inhibition of ovulation by suppressing Follicular Stimulating Hormone (FSH), thus suppressing the release of ovum from ovaries
- ii. Preventing implantation by altering endometrium so that it is not conducive for implantation
- iii. Reducing transportation of sperms by making cervical mucus thick.
- Continuous taking of the COC for 7 days is critical for suppressing the ovulation.
- Each tablet's effect lasts only for 48 hours.

1.3 Effectiveness

It is very effective when taken correctly and consistently and the failure rate is 0.2 - 1 per 100 women years.

1.4 Advantages of COC

1.4.1 Contraceptive benefits

- i) Very effective when taken correctly and consistently and protects against both uterine and ectopic pregnancy.
- ii) Safe for most women
- iii) Easy to use
- iv) Reversible (can stop the COC whenever desired by the client on her own and immediate return of fertility is experienced)
- v) Non-invasive
- vi) Unrelated to sexual activity

1.4.2 Health benefits

- i) Menstrual cycle
 - Decreases menstrual blood loss and the duration
 - Decreases menstrual cramps and pre-menstrual tension as cycles are anovulatory due to suppression of ovulation
 - Eliminates mid-cycle ovulation pain as no ovulation
 - Ensures regular 28 day menstrual cycle
- ii) Does not worsen anaemia due to less menstrual blood loss
- iii) Reduces incidence of severe Pelvic Inflammatory Disease (PID) as compared to nonusers. The mechanisms contributing to less severity of PID in women who are COC users are the following: Decreased chances of growth of micro-organisms due to decreased menstrual blood, reduced

chances of the organisms entering the uterus through thickening of cervical mucus and reduced chances of spread due to less stronger uterine contractions.

Although the COC reduces the chances of severe PID, it does not offer protection against all types of PID such as that caused by Chlamydia.

- iv) Protection from ovarian and endometrial cancers and functional ovarian cysts
- v) Protection from benign breast tumours such as fibroadenoma and fibrocystic disease
- vi) Used in treatment of endometriosis and abnormal bleeding
- vii) Relief from acne especially pre-menstrual type due to the oestrogen
- viii) Decreases incidence of rhuematoid arthritis

1.5 Disadvantages

1.5.a Limitations

- i) Has to be taken every day and depends on the motivation of the user
- ii) Does not protect against Sexually Transmitted Diseases (STDs)/HIV/AIDS
- iii) Not appropriate for mothers who are breast feeding infants less than six months old
- iv) Effectiveness of the COC may be decreased in women who are taking the following drugs:
 - * Anti epileptic drugs
 - Anti tuberculosis drugs
 - * Antibacterial drugs
 - Anti fungal drugs

It also interferes with the effectiveness of certain drugs. The list of drugs that affect the effectiveness of COC and those affected by the COC are given in Annexure 1.

1.5.b Side effects

- Minor side effects listed below are most common during the first three months of use of COC and these usually disappear with continued use.
- · Amenorrhoea
- Inter-menstrual bleeding or spotting (breakthrough bleeding)
- Nausea
- · Headache
- · High blood pressure
- Weight gain
- Breast tenderness

Minor side effects are most common in the first three months of COC use.

These disappear with continued use of the COC.

ii) Serious side effects such as heart attack or stroke are rare with low dose COCs. However, the risk is high among women who smoke, particularly those above 35 years, Women who smoke, irrespective of whether they use COC are at increased risk for the above complications.

2. Counselling

2.1 Counselling for family planning

Counselling is one of the critical activities under family planning services. Every client should be counselled to help decide to plan her/his family and to choose a method based on informed choice. Wherever possible spouse/ partners should be counselled.

Effective counselling involves:

- i) Building a rapport with the client by greeting the client and making the client feel comfortable.
- ii) Identifying the client's needs by asking relevant questions: personal, social, family, medical, reproductive health including reproductive tract infections/ STDs, family planning goals and past/current use of family planning methods.
- iii) Providing information to the clients on:
 - Benefits of family planning focusing on specific benefits for the woman, the children and the family.
 - Various contraceptive methods including mechanisms of action of methods, their benefits and disadvantages and timing for initiation of the method.
 - Where to go for care if the health facility does not provide a particular method
- iv) Helping the client chose a method and assessing whether the method chosen is appropriate. If the chosen method is not appropriate, explain the reason and help chose another method.

- v) Providing method-specific information and providing the contraceptive. In case of methods not available in the facility, provide information and other assistance to get the appropriate method.
- vi) Discussing when to return for supplies and follow up and in case of problems.

Confidentiality and privacy must be ensured at all counselling sessions.

Confidentiality and privacy should be maintained during counselling.

2.2 Method-specific counselling

Once a client has chosen COCs for family planning, then method specific counselling is done as follows. Counselling is done every time a client comes for re-supply. Ensure that privacy and confidentiality are maintained all the time.

- i) Establish rapport with the client.
- ii) Ask the client what she knows about COC, rumours (if any) and past experience with COC (in case of clients who have used 'the pill'). (Refer to Annexure 2 for common rumours).
- Provide information as relevant and clarify doubts. If the client is new, repeat the information on the following. Show a packet of COC.
 - Mechanism of action
 - Advantages, disadvantages
 - Effectiveness
 - ♦ When to start taking the COC (in relation to menstrual period)
 - The importance of taking the COC everyday and what to do if the pill is missed

- iv) If the client is still convinced about the decision to use COC, conduct an assessment of the client for medical eligibility as detailed in Section 4. Record history and findings in the client record.
- v) If found eligible as described in Section 3, demonstrate the use of the COC as advised in Section 5. Ask the client to repeat instructions. Record the supply of the COC.
- vi) Tell the client about likely problems /side effects in the first few months and what to do in such situations.
- vii) Tell the client about likely serious problems (warning signs) when the client must contact the Medical Officer /health worker and assure that care will be provided.
- viii) Tell the client to use condoms (by spouse/partner) if the COC is missed, in case of severe vomiting or diarrhoea and if there is any chance of exposure to STDs and demonstrate how to use condoms.

 Ask the client to repeat the instructions.
- ix) Tell the client to inform the health provider if started on treatment for tuberculosis or epilepsy.
- x) Tell the client to inform the health provider about taking COC when seeking medical consultation
- xi) Tell the client how to store the COC.
- xii) Tell the client to return for follow up in a month's time and to bring the used packet of COC.
- xiii) Provide three packets of COC. Tell the client about other sources of COC, which she can use if needed.
- xiv) Provide a packet of condoms for use in conditions listed above (see viii).

2.3 Counselling on return visit

Every time a client comes for follow-up, it is important to counsel the client to ensure continuation of the method.

- i) Ask the client whether she and her spouse/partner are satisfied with the method
- ii) Ask about problems and reassure as required.
- iii) Ask about any history of pelvic pain or discharge per vagina or any history suggestive of STDs in the spouse/partner
- Assess the client by history and examination to confirm problems or for any new conditions that are contra-indications for use of COC.

 Record findings.
- v) Manage problems as discussed in Section 6.
- vi) If the client has developed conditions that are contra-indications for COC use, counsel for other methods of family planning.
- vii) If the client is still eligible for continuing with COC, ask to repeat how to take the COC.
- viii) Repeat reasons for contacting the health worker and when to return for follow up.
- ix) Provide supplies of COC and record the same.

2.4 Counselling a client who wants to stop using the COC

It is important to counsel a client who wants to stop using the COC because of request by the client or because of contra-indications/complications. It is important to tell clients about immediate return of fertility after stopping the COC.

- i) If the client wants another child, tell about immediate return of fertility. Provide information on antenatal care, care during delivery and about post-partum family planning.
- ii) If the client is stopping the COC due to side effects, which have persisted in spite of management of the problem, counsel for other methods of family planning.
- iii) If the client is stopping the COC because of dissatisfaction with the method, counsel (repeat benefits, side effects and their duration). If still not convinced, counsel about other methods of family planning.
- iv) If the client develops conditions that are contra-indications for use of COC, counsel about other methods of family planning.
- v) Record findings, reasons for stopping the use of COC and advice.

3. Eligibility criteria for use of COC

3.1 Indications

Appropriate for:

- i) Any woman in the reproductive age group, who desires a highly effective contraceptive
- ii) Immediately after abortions
- iii) Women with menstrual problems such as severe cramps, heavy bleeding or has irregular cycles
- > COC decrease cramps, bleeding and regularises cycles.
- iv) Has moderate to severe anaemia
- Less menstrual blood loss with COC and therefore does not worsen the anaemia.
- v) History of functional ovarian cysts and family history of ovarian cancer
- > COC provides protective effect against the above conditions.

3.2 Precautions

3.2.a Absolute Contraindications

COC should not be prescribed in the following conditions/ situations:

- i) Pregnancy
- ii) History of thromboembolic disorders in the present or past:
 - Deep vein thrombosis
 - Stroke
- Destrogen promotes blood clotting and adds to the existing predisposition to thrombosis.

- iii) History of heart disease
 - · Ischaemic heart disease
 - Heart problems such as angina, cardiac failure, valvular heart disease
 and others
- > The increased risk of thrombosis with the oestrogen adds to the predisposition to thrombosis in the above conditions.
- iv) High blood pressure 160 +/100+
- > Oestrogen increases the blood pressure slightly and thus adds to the existing risk situation.
- v) Severe headache or migraine with focal neurological symptoms
- > This may be an indication of increased risk of stroke, a condition in which the COC is contraindicated.
- vi) Long standing diabetes or diabetes with vascular disorders such as retinopathy, nephropathy or neuropathy
- The COC adds to the increased risk of cardiovascular disease and thrombosis.
- vii) Is above 35 and is a heavy smoker (15 cigarettes/'bidis' a day)
- > Smoking as such is a risk factor for cardiovascular problems and oestrogen adds to the risk. Smoking and oestrogen promote blood clotting.
- viii) Has a known carcinoma of breast or has history suggestive of carcinoma or undiagnosed lump
- The risk for progress of the condition may be increased. In case of an undiagnosed lump, indication for use is based on confirmed diagnosis.

- viii. Has severe or active liver disease, gall bladder disease or history of jaundice in the previous six months or recurrent jaundice during pregnancy
 - The COC is metabolised in the liver and its use may adversely affect women whose liver function is already compromised. COC may affect the prognosis of the existing liver tumours. It may worsen the existing gall bladder disease.
 - ix. Breast feeding less than six weeks postpartum
 - Destrogen increases the risk of thrombosis (adds to the existing risk of thrombosis during early post-partum period). There is also the risk of neonates getting a dose of oestrogen through breast milk.
- x. Known carcinoma of the cervix or history suggestive of carcinoma (unexplained vaginal bleeding: intermenstrual or post-coital)
- There is minimal chance of carcinoma in situ progressing to invasive disease and the progression of existing carcinoma. The risk is increased with smoking and unsafe sexual practices.

3.2.b Relative contraindications

COC should be considered more carefully in the following conditions:

- i) Breast feeding six weeks to six months post-partum
- > COC may decrease quantity of breast milk.
- ii) Age over 40 years
- > Risk of cardiovascular disease increases and COC may add to the risk.
- iii) Smoker and age above 35 years
- iv) History of hypertension or current blood pressure above 140/90

It is advisable to consult a specialist before starting the COC in the following condiitons.

- v) Known hyperlipidemia
- > Oestrogen may add to the existing risk.
- vi) Unexplained vaginal bleeding
- > It may be due to pregnancy (tubal or uterine) or pelvic pathology such as malignancy, ovarian cysts, PID or fibroids. COC has a protective effect in case of ovarian cysts, endometrial and ovarian cancers. It is important to diagnose the cause before prescribing COC.
- vii) On treatment for tuberculosis or epilepsy or on antibiotics for more than a week
- > These drugs reduce the efficacy of COC.

3.2.c Special circumstances when COC should not given

- i) Planned surgery: COC should be discontinued at least four weeks in advance of the surgery because of its effect on increasing coagulation of blood.
- ii) Adolescents who have not reached menarche

4. Client assessment

4.1 History taking

History should be taken very carefully. The history should include the following:

- Age, smoker (if smoker: number of cigarettes per day)
- Date of last menstrual period and details of menstrual cycle
- · Parity, date of last child birth/abortion
- Whether breast feeding (if breast feeding, age of the child and whether breast feeding is exclusive or partial)
- History of hypertension, heart problems, breathlessness, deep vein thrombosis (severe pain and swelling in the calf) and stroke
- History of severe headaches
- + History of jaundice (including during pregnancy) and liver disease
- History of lumps in the breast or breast cancer
- History of cancer of the cervix and uterus
- Any bleeding between periods or after intercourse
- History of pelvic infections or sexually transmitted diseases (abnormal vaginal discharge, lower abdominal pain)
- Whether on treatment for tuberculosis or convulsions or taking antibiotics for long

4.2 General and systemic examination

General physical: Weight, pallor, jaundice, cyanosis, pulse, blood pressure

Heart: Rate

Breast: Lumps, ulcer (see Annexure 3 for breast examination)

Abdomen: Liver (whether enlarged, tender), any mass, tenderness in the lower abdomen

4.3 Pelvic examination

Conduct the following examinations as described in Annexure 4.

- i) Examination of external genitalia for evidence of Reproductive Tract
 Infections (RTIs)/STDs
- ii) Speculum examination for evidence of vaginal and cervical infection, and cervical growth/ulcers
- Bimanual examination for determining the uterine size, consistency, mobility, tenderness and adenexal mass (ovarian cyst/cancer) and for ruling out PID

4.4 Laboratory examination

It is advisable to get the haemoglobin and urine for sugar checked.

Do a Pap smear if possible and a vaginal smear for infections if indicated.

4.6 Record

Record the findings in the COC screening and follow up card (see Annexure 5).

If any contraindication present, do not provide COC.

5. Guidelines for instructing a client on use of COC

5.1 Steps for instructing a client:

- i) Show the packet of COC to the client as instructions are being given.
- ii) Explain the timing of starting 'the pill'.
 - Start 'the pill' on the fifth day of menstruation (explain that the first day of menstruation is the day when bleeding/spotting starts). Explain that it is important to start 'the pill' on day five as by then menstrual flow will be full and one can be sure of not being pregnant.
- iv) Explain how to take 'the pill'
 - Show the client where to start 'the pill' (where it is marked START) and to follow the arrow to decide which pill to take next and follow the arrow till the last pill.
 - Show how to take out the pill from the packet.
 - Emphasise the importance of taking 'the pill' everyday even during menstruation and even when there is no sexual intercourse.
 - Explain that 'the pill' must be taken at a fixed time, preferably at night before going to sleep. This will help to prevent the feeling of nausea, which is common in the early months of taking the pill.
 - Tell that the day after the packet is over, the next packet should be started with 'the pill' where it is marked START.
 - Explain that 'the pill' has to be taken <u>continuously</u> for 7 days for it to be effective in preventing pregnancy.

- v) Explain that the client may suffer from spotting or bleeding between periods and nausea during the first three months. Tell the client that taking 'the pill' at night helps to avoid nausea. Emphasise that the problems usually disappear after the first three months.
- vi) Tell the client what to do in case 'the pill' is missed. Emphasise that each day of missing 'the pill' increases the risk of pregnancy.
 - ♦ If one pill is missed, take it as soon as you remember it.
 - The next pill should be taken at the same time as usual (two pills may have to be taken on one day).
 - ♦ If the pill is missed for two days or more:
 - Take the pills as soon as possible and continue with the packet. Two tablets should be taken for the number of days the pill has been missed. (Although the pill is not effective if missed for 48 hours (2 days). the continuation of the pill is being advised to maintain the routine.)
 - Use condoms for 7 days, till the pill has been taken for 7 continuous days (for the pill to be effective).

vii) Advise use of condoms:

- ♦ If 'the pill' is missed for two or more days
- ♦ If the packet of COC is finished and she has no new packet
- ♦ If risk of exposure to STDs
- In case of diarrhoea or vomiting when the chances of absorption of the pill are less and the risk of pregnancy is increased
- viii) Instruct the client to inform about the use of 'the pill' during every medical consultation to prevent prescription of drugs that have interactions with the COC.

- Advise the client to contact for advice if started on treatment for tuberculosis, epilepsy or on long term antibiotics as these drugs decrease the effectiveness of the COC.
- x) Advise to keep the COC in a cool, dry place, away from the reach of children.
- xi) Give instructions for follow up.
 - Return to the clinic within three months of starting the COC.

 Advise to bring the used packets (even the empty ones to be sure that the pills are being taken regularly).
 - Return to the clinic before the scheduled date if:
 - not satisfied with the method
 - develops jaundice
 - pregnancy suspected
 - at risk of STD/HIV
 - develops lumps in the breast
 - has inter-menstrual or post-coital bleeding
- xii) Contact immediately if any of the following as they are life threatening conditions:
 - ♦ Severe abdominal pain (probably gall bladder disease, blood clot or pancreatitis)
 - ♦ Severe chest pain, cough, breathlessness (probably blood clot in the lungs or heart attack)
 - ♦ Severe headache, dizziness, weakness, numbness (probably due to stroke, hypertension or migraine)
 - ♦ Eye problems (loss of vision or blurring), speech problem (probably due to stroke or temporary vascular problem)

- ♦ Severe pain (calf or thigh) (probably blood clot in the leg)
- xii) Provide a packet of condoms. Demonstrate the use of condoms if the client does not know and ask to repeat the same.

Warning signs

The following acronym will help to remember the warning signs.

- A- Abdominal pain
- C Chest pain
- H Headache
- E Eye problem
- 5 Severe leg pain

5.2. Record

Record the supply of the COC.

5.3 Follow up schedule

During each follow up visit, the client should be counselled as described in Section 2.

The Medical Officer should instruct the HW(F) that during her routine field visits she should enquire about any problems and advise clients for follow-up.

The recommended schedule for follow-up assessment is as follows:

First visit - Within three months of prescribing the COC

Subsequent visits - Yearly

Do a complete assessment during the yearly visits. Record findings.

Do haemoglobin and urine for sugar.

The client must be instructed about taking 'the pill' regularly.

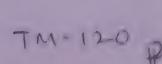
6. Management of side effects and other complications

Always counsel clients who have side effects and other complications as described in Section 2. If the COC is stopped, counsel for other methods of family planning.

6.1. Amenorrhoea

- i) Ask the client to explain how she has been taking 'the pill' (see the used packet if available, to be sure that no pill has been missed).
- ii) Ask for history of diarrhoea and vomiting, whether started on treatment for tuberculosis, epilepsy or any antibiotics.
- iii) Rule out pregnancy by history and examination.
 - If pregnant and does not want to continue with the pregnancy,
 refer for Medical Termination of Pregnancy (MTP).
 - If pregnant and wants to continue with the pregnancy, reassure that 'the pills' taken so far won't affect the foetus. Advise about antenatal care.
- iv) If 'the pill' is being taken regularly and if the client is not pregnant, reassure the client. Explain that no menses is due to lack of build up of the uterine lining.
 - ◆ If the client is reassured, advise to complete the second packet of 'the pill' and report for follow up.
 - If the amenorrhoea continues after the second packet is over, refer to a specialist.

31



6.2 Spotting or bleeding between periods

- i) Ask the client to explain how she has been taking 'the pill' (see the used packet if the client has brought it).
- ii) Ask for history of diarrhoea and vomiting, whether started on treatment for tuberculosis, epilepsy or any antibiotics.
- iii) Rule out pregnancy and other gynaecological problems such as tumours, PID or cervical infection by history and examination.
- iv) If pregnant, advise according to intentions of continuing with the pregnancy (see iii under 6.1 Amenorhhoea).
 - ♦ If evidence of infection, take smears and treat.
 - Take pap smear if possible and send it to an appropriate facility for diagnosis and refer to a specialist if required.
- v) If 'the pill' is being taken regularly and she is not pregnant, reassure the client.
 - If the client is reassured, advise to complete the second packet and report for follow up.
 - If the spotting persists even after the second cycle, refer to a specialist.

6.3 Nausea

- i) Ask the client to explain how she has been taking 'the pill' (see the used packet if the client has brought it).
- ii) Find out the timing of taking 'the pill'.
- iii) Rule out pregnancy by history and examination.
 - If pregnant, advise according to intentions of continuing with the pregnancy (see iii under 6.1 Amenorhhoea).
- iv) If not pregnant, rule out other causes of vomiting such as jaundice.

- v) If 'the pills' are not taken at night, advise to do so.
- vi) If the client wants to continue with 'the pill', reassure and explain that the symptoms generally disappear after three months.
- vii) If on high dose oestrogen or progestogen, prescribe low dose pills.

6.4 Headaches

- i) Rule out causes of headache such as sinusitis and eye problems. Treat accordingly and continue with the COC.
- ii) Check blood pressure. If blood pressure is high, manage as described under 6.5 High blood pressure.
- Rule out migraine. Ask for history of blurring of vision, numbness and speech problems. If history suggestive of migraine, stop the COC and counsel for other methods of family planning.

6.5 High blood pressure

- i) Ask for history of high blood pressure prior to starting 'the pill'.
- ii) If blood pressure is higher than 160/100, stop the COC. Advise for treatment (if not already on treatment). Counsel for another method of family planning.
- of rise in blood pressure due to the pill. If wants to continue with the pill, advise to get blood pressure checked every month and to get treatment for high blood pressure (if not already on treatment). Put on a low dose pill (if on high dose pill).

6.6 Weight gain

- i) Check whether the weight gain is after the COC has been started.
- ii) Find out about eating habits.
- iii) If no reason for weight gain, rule out pregnancy. If pregnant, advise as in iii under 6.1 Amenorrhoea.
- iv) If not pregnant, reassure that hormonal contraceptives do cause slight weight gain. If weight gain is not acceptable, stop the COC and counsel for another method.

6.7 Breast tenderness

- i) Rule out pregnancy and advise accordingly.
- ii) Rule out breast lumps and in case of lumps, rule out cancer of the breast.
- iii) If breast feeding, rule out infection.
- iv) Reassure. Put on low dose pill (if on high dose) or switch over to progestogen pill.
- v) Reassure.

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Part B: Centchroman

1. Introduction to Centchroman

1.1 Centchroman

Central Drug Research Institute, Lucknow. Many years of research has shown that the drug is very effective in preventing pregnancy and has minimal side effects. The product was made available in the market at a subsidised price by Hindustan Latex Limited, a public sector undertaking, under the trade name "Saheli". The product is one of the socially marketed contraceptives of the Government of India.

The product, initially introduced in Uttar Pradesh and Delhi, was made available in other parts of India. The post-marketing surveillance study of 1996, done all over the country, involving senior obstetricians and gynaecologists, has shown that about 100,000 women have been using 'Saheli' and have not reported any serious side effects. The increasing acceptability of the method has prompted large scale community based studies in other areas of India such as the study in Medek in Andhra Pradesh. The findings of the study have further corroborated the earlier findings about efficacy of the product and fewer side effects.

1.2 Mechanism of Action

Centchroman acts by inhibition of implantation of embryo in the uterus. Synchrony between the development of embryo and its movement into uterine cavity and the changes in the uterine lining is essential for implantation of the embryo.

Centchroman acts by:

- i) Suppression of uterine proliferation and decidualisation and alteration of biochemical parameters of implantation
- Mild stimulation in tubal transport of embryo (that causes the embryo to move into the uterine cavity before it is ready to receive the embryo) and blastocyst development and delayed shedding of Zona Pellucida (the covering of the ovum)

The above changes cause asynchrony between the embryo and changes in the uterus, critical for nidation (embedding)

1.3 Effectiveness

It is very effective when taken correctly and consistently. The failure rate is 1-2 per 100 women years of use.

1.4 Advantages of Centchroman

- i) It is a non-steroidal contraceptive
- ii) Very effective
- iii) Minimal side effects as it is non-steroidal, has no effect on ovulation and does not cause any hormonal change

1.5 Disadvantages

- i) Once-a-week pill, hence the chances of forgetting the pill are higher
- ii) Menstrual changes such as delayed menses
- iii) More expensive than COC
- iv) Fertility returns only after six months of stopping the pill

2. Counselling

Method- specific counselling

Once a client has chosen Centchroman for family planning, then method specific counselling is done as follows. Counselling is done every time a client comes for resupply. Ensure that privacy and confidentiality are maintained all the time. Wherever possible spouse/partners should be counselled.

- i) Establish rapport with the client.
- ii) Ask the client whether she has heard about Centchroman ("Saheli").

 If she knows about Centchroman, ask about rumours (if any) and past experience with Centchroman (in case of clients who have used the pill)
- Provide information as relevant and clarify doubts. If the client is new, repeat the information on the following. Show a packet of Centchroman.
 - Mechanism of action
 - Advantages, disadvantages
 - Effectiveness
 - When to start taking the pill (in relation to menstrual period)
 - The importance of taking the pill everyday and what to do if the pill is missed
- iv) If the client is still convinced about the decision to use Centchroman, conduct an assessment of the client for medical eligibility as detailed in Section 4. Record history and findings.

- v) If found eligible as described in Section 3, demonstrate the use of the pill as advised in Section 5. Ask the client to repeat instructions. Record the supply of the pill.
- vi) Tell the client about likely side effects and what to do in such situations.
- vii) Tell the client to use condoms (by spouse/partner) if the pill is missed, in case of severe vomiting or diarrhoea and if there is any chance of exposure to STDs and demonstrate how to use condoms.

 Ask the client to repeat the instructions.
- viii) Tell the client how to store the pill.
- ix) Tell the client to return for follow up in a month's time (before the last pill is over and to bring the packet of pills).
- x) Tell the client where to get the pills and the price.
- xi) Provide a packet of condoms for use in conditions listed above (vii).

2.3 Counselling on return visit

2.3.1 General guidelines

Every time a client comes for follow-up, it is important to counsel the client to ensure continuation of the method.

- i) Ask the client whether she and her spouse/partner are satisfied with the method
- ii) Ask about problems and reassure as required.
- iii) Ask about any history of pelvic pain or discharge per vagina or any history suggestive of STDs in the spouse/partner
- iv) Assess the client (history and examination) to confirm problems or for any new conditions that are contra-indications for use.

- v) Manage problems as discussed under Section 6.
- vi) If the client has developed conditions that are contra-indications for Centchroman use, counsel for other methods of family planning.
- vii) If the client is still eligible for continuing with Centchroman, ask to repeat how to take the pill.
- xii) Repeat reasons for contacting the health worker and when to return for follow up.

2.3.2 Guidelines for second follow up visit (after three months of starting the pill)

In addition to the above, tell the client to take the pill once-a-week, on a specific day instead of twice-a-week.

2.4 Counselling clients who want to stop using the Centchroman

It is important to counsel clients who wants to stop using the Centchroman, because of request by the client or because of contra-indications.

- i) If the client wants another child, <u>tell that the fertility will return</u> only after six months. Provide information on antenatal care, care during delivery and about post-partum family planning.
- ii) If the client is stopping the Centchroman due to delayed menses, reassure the client. If not reassured, advise to discontinue the Centchroman. Counsel about other methods of family planning.
- iii) If the client is stopping the Centchroman because of dissatisfaction with the method, counsel (repeat benefits, side effects and their duration). If still not convinced, counsel about other methods of family planning.

iv) If the client develops conditions that are contra-indications for use of Centchroman, counsel about other methods of family planning.

3. Eligibility criteria for use of Centchroman

3.1 Indications

Appropriate for:

- i) Any woman in the reproductive age group, who desires a highly effective contraceptive with minimal side effects
- ii) Immediately after abortion

4.2 Precautions

4.2.1 Absolute contraindications

Centchroman should not be given in the following conditions:

- i) History of jaundice or diseases of liver now or in the last 6 months
- ii) History of polycystic ovarian disease
- iii) Cervical displasia

4.2.2 Relative contraindicatins

Centchroman should be considered carefully in the following conditions:

- i) History of tuberculosis
- ii) History of kidney disease
- iii) Lactating mothers in the first six months postpartum

4. Client assessment

4.1 History taking

History should be taken very carefully. History should include the following:

- Date of last menstrual period and details of menstrual cycle
- Parity, date of last child birth/abortion
- Whether breast feeding (if breast feeding, age of the child and whether breast feeding is full or partial)
- History of jaundice and liver disease currently or in the last six months
- History of kidney problems
- Any swelling of the face and feet currently or in the past
- History of cancer of the cervix
- Any bleeding between periods or after intercourse
- Whether on treatment for tuberculosis or convulsions or taking
 antibiotics for long
- If any contraindication, confirm by relevant physical and pelvic examination. Do not provide Centchroman.

4.2 General and systemic examination

General physical: Weight, pallor, jaundice, oedema, blood pressure

Abdomen: Liver (whether enlarged, tender), any mass, tenderness in the
lower abdomen, check for renal tenderness and mass

4.3 Pelvic examination

Conduct the following examinations as described in Annexure IV.

- i) Examination of external genitalia for evidence of STDs
- ii) Speculum examination for evidence of vaginal and cervical infection, and cervical growth/ulcers
- Bimanual examination for determining the uterine size, consistency, adenexal mass (ovarian cyst/cancer) and for ruling out PID

4.4 Laboratory examination

It is advisable to get the haemoglobin and urine for sugar, albumin and microscopy checked.

Do a Pap smear if possible and a vaginal smear for infections if indicated.

4.6 Records

Record the findings.

5. Guidelines for instructing a client on use of Centchroman

5.1 Steps for instructing a client:

- i) Show the packet of Centchroman to the client as instructions are being given.
- ii) Explain the timing of starting the pill and the schedule to be followed.
 - Take the first tablet on the first day of the menstrual period.
 - Take the second tablet on the fourth day.

- Take the subsequent tablets twice a week on the same days of the week (recommend Wednesday and Sunday) for the first 3 months.
- After the first 3 months, take the tablet once a week on the same day of the week.
- iii) Explain that the periods may be delayed
- iii) Explain what to do if the pill is forgotten.
 - If one pill is forgotten, take it the next day as soon as you remember it.
 - If you forget it for 2 or more days, but less than 7 days, continue normal schedule, but use condoms to be sure of preventing pregnancy.
 - If forgotten for more than 7 days, discontinue and start all over again beginning with the next menstrual period. Meanwhile use condoms as a backup method.
- iv) Use condoms in the following situations:
 - in case of severe vomiting and diarrhoea
 - in case of exposure to STDs or HIV
- v) Advise where to get the Centchroman and the price.
- vi) Advise to keep the pills in a cool, dry place, away from the reach of children.
- vii) Provide a packet of condoms. Demonstrate the use of condoms if the client does not know how to use. Ask the client to repeat the demonstration.
- viii) Give instructions for follow up.

- Return to the clinic before the last pill is over. Bring the packet (even the empty ones). (This is to be sure that the pills are being taken regularly).
- Return to the clinic before the scheduled date if:
 - not satisfied with the method
 - develops jaundice
 - started on treatment for tuberculosis
 - if cervical displasia or cancer is diagnosed or has intermenstrual or post-coital bleeding
 - if pregnancy suspected
 - if at risk of STD/HIV

5.2 Record

Record the supply of the pill.

5.3 Follow up schedule

During each follow up visit, the client should be counselled as in Section 2.

The Medical Officer should instruct the HW(F) that during her routine field visits she should enquire about any problems and advise clients for follow-up.

The recommended schedule for follow-up assessment is as follows:

First visit - After one month of prescribing Centchroman

Second visit - After three months of prescribing the Centchroman

Subsequent visits - Yearly

Do a complete assessment during the yearly visits. Record findings.

Do haemoglobin and urine for albumin.

The client must be instructed about taking 'the pill' regularly.

6. Management of side effects and other complications

Always counsel clients who have side effects and other complications as described in Section 2. If the Centchroman is stopped, counsel for other methods of family planning.

Delayed menses

- i) Rule out pregnancy by history and examination.
 - ◆ If pregnant and do not want to continue with the pregnancy, refer for Medical Termination of Pregnancy (MTP).
 - If pregnant and want to continue with the pregnancy, reassure that the pills taken so far won't affect the foetus. Advise about antenatal care.
- ii) If the pill is being taken regularly and there is no evidence of pregnancy, reassure the client. Explain that it is common to have delay in menses with Centchroman.

References

- 1. Hindustan Latex Limited: 'Saheli' Oral Contraceptive Pill. Product Monograh.
- 2. Hindustan Latex Limited: 'Saheli' Oral Contraceptive Pill. Information leaflet.
- 3. CDRI Lucknow: Notes on Centchroman

Annexure 1 Drug Interactions

A. Drugs that may reduce the efficacy of COCs					
Antibacterials	Anticonvulsants	Antifungals			
Rifampicin	Barbiturates (Pheno- barbitone, Primidone	Griseofulvin			
Penicillins					
Chloramphenicol					
Cephalosporins					
Metronidazole					
Sufonamides					
Nitrofurantoin					
B. Drugs that are affect	ed by COC				
Antibacterials	Anticonvulsants	Anticoagulants			
Trolendomycin	Barbiturates:Phenytoin	Warfarin			
(increases toxicity)	(increases toxicity)	(decreases effect)			
Antidepressants	Antidiabetic agents	Antihypertensive agents			
Tricyclic:clomipramine,	Insulin	Methyl dopa			
amitryptiline	Oral hyoglycaemics	(decreases effect)			
(increases effect)	(decreases effect)	Beta blocking agents			
Antionviot		(increases effect)			
Antianxiety	Theophylline preparations				
Benzodiazepines:	Aminophylline				
Chlordiazepoxide,	Theophylline				
diazepam	(increases risk of				
(increases the effect of the above)	toxicity)				
Lorazepam (decreases effect)	1-				

Source: ICMR: Guidelines for Family Planning Services including Counselling. Screening, Procedure, Follow-up and Infection Control. Module for PHC Medical Officers 1996.

Annexure 2 Rumours and facts

One of the reasons for a smaller percentage of women using COC is the myths about the COC. The following is a list of common myths and the facts. It is important to be aware of these to effectively counsel the clients who opt for COC.

Myths

1. Pill causes cancer.

2. Pill causes infertility.

3. Pills cause heat in the body and need to drink milk to decrease the effect.

Most clients cannot afford to buy milk.

Facts

Pills offer protection against cancers of the ovary and endometrium. There is no demonstrated increase in risk of breast cancer.

Pills do not lead to permanent infertility.

After stopping the pill fertility returns immediately in most women.

The pills do not cause any heat in the body. It does not cause hyperacidity.

Milk has no effect on the side effects of the pill.

Myths

5 Pill affects women's health permanently.

5. Pills cause deformities in babies.

6. Pills must be discontinued for 2-3 months as continued use may cause ovarian dysfunction.

Facts

The low dose pills do not lead to major complications, as the dose of hormones is small.

Experiences from India and all over the world have shown that if the women are properly screened and the pill is given only to the women who are eligible for use, then there are no serious complications.

The risk of dying from pregnancy and childbirth is higher than the risk of dying from complications of the pill.

There is no increased risk of giving birth to deformed babies by women who have taken COC. Even when the pill is taken accidentally during pregnancy, there is no risk of the baby being born deformed. The pills can be safely used continuously, as long as one desires. Fertility returns immediately after stopping the pill in most women. Discontinuation of use of pills without using another method can lead to an unwanted pregnancy. There is no need to advice few months of 'no pill'

Annexure 3

Breast examination

- 1. Explains the procedure to the woman
- 2. Instructs the woman to do the following:
- Disrobe up to the waist fully exposing the breasts (ensure privacy)
- · Stand with arms raised
- 4. Look for:
- Symmetry
- Ulcer
- · Skin pitted like orange skin
- · Position of the nipple
- * Discharge from the nipple
- 3. Put hands on hips and repeat the inspection
- 4. Make the woman lie with left hand behind the head
- 5. Palpate the left breast using the flat of the fingers, starting with the left axilla and moving the fingers slowly towards the nipple and feel for lumps (both in the breast and axilla).
- 6. Squeeze the nipple for any discharge.
- 7. Put the right hand under the head and palpate the right breast the same way.

Make the woman repeat the instructions and examination. Ask her to stand in front of the mirror while inspecting the breasts. Tell her the best time is one or two weeks after the periods (tell that just before periods it is normal for some women to have fullness and tenderness in the breast due to hormonal changes in the body)

TM-120

Annexure 4

1. Equipment and supplies for pelvic examination

- i) Sim's/Cusco's speculum
- ii) Anterior vaginal wall retractor
- ii) Gloves
- iii) Sterilised cotton swabs and swab stick in a jar with lid.
- iv) Kidney tray for keeping used instruments
- i) Bowl for antiseptic solution
- ii) Antiseptic solution: Chlorhexidine 1% or Cetrimide 2%

 Ensure that the antiseptic solution is freshly prepared.

 If Povidone Iodine solution is available, it is preferable to use it.
- iii) Cheatles Forceps
- ix) Proper light source/torch
- > In addition, it is advisable to keep the following ready for vaginal and Pap smears:
- For vaginal smear: Clean slides with cover slips, cotton swab sticks, KOH solution and saline in bottles with droppers
- For Pap smear: Ayre's spatula, clean slides and fixing solution/hair spray
- > Instruments and gloves must be autoclaved. In case autoclaving is not possible, the instruments must be fully immersed in water in a covered container and boiled for at least 20 minutes after the water has started boiling.

2. Preparation

- i) Ensure that the equipments and supplies for pelvic examination are ready.
- ii) Explain the various procedures to the client and continue to explain before each step.
- iii) Ask the client to empty her bladder and lie down on the table on her back with knees flexed.
- iv) Protect the client's privacy.
- v) Wash and scrub hands. Wear sterile gloves taking care that the outer side of gloves does not get contaminated.

3. Examination of external genitalia

Inspect the external genitalia: labia majora, minora and introitus for redness, patches, ulcer, growth, warts, swelling and discharge.

If any evidence of infection or STD, treat or refer to a specialist

4. Speculum examination

Do a speculum examination as follows. (Explain the steps to the client)

- i) Clean the introitus and labia with antiseptic solution.
- vaginal canal. When the blades are halfway, turn them to the horizontal position. In case of Cusco's speculum, gently open the blades to find the cervix, taking care not to injure any tissue. In case of Sim's speculum, use the anterior vaginal wall retractor to visualise the cervix. Apply little downward pressure on the posterior (lower vaginal wall) and gently move

the speculum further closer to the cervix. (Figure 1)

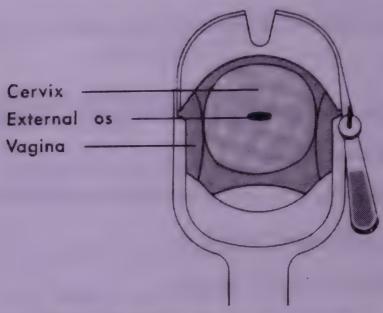


Figure 1: Speculum examination

- iii) Inspect the vagina and cervix for ulcer, abnormal discharge, cysts, polyp, growth and bleeding sites.
- Treat or refer to a specialist if any of the above are present.
- iv) If abnormal discharge is seen, use cotton swab to collect specimen for microscopic examination using KOH and normal saline. Take Pap smear if indicated and if the facility is available or refer.
- v) Remove the speculum by turning the blades obliquely (close the speculum first in case of Cusco's) and keep in the sterile kidney tray.

5. Bimanual examination

Perform bimanual examination as follows: -

- i) Separate the labia.
- ii) Introduce two fingers of the right hand into the vagina and put the other hand on the abdomen above the pubic symphysis.

- Using the two fingers in the vagina, follow the anterior vaginal mucosa into the anterior fornix and locate the cervix.
 - Feel the cervix for consistency, mobility, tenderness on movement, irregular or hard area on the cervix and any bleeding to touch.
- Refer to a specialist if the movement of the cervix is painful as it is indicative of PID or if the cervix is not mobile or hard or bleeds to touch as it is indicative of carcinoma of the cervix.
- iv) With the 'abdominal' fingers, gently apply pressure downward above the pubic symphysis to steady the pelvic organs. Place the 'vaginal' fingers anterior to the cervix and feel the uterus between the fingers of both hands as shown in Figure 2. If the uterus is anteverted (lies anterior to the cervix), the entire uterus will be felt between both the hands. If the uterus is not palpated anteriorily, then the uterus may be retroverted.
- v) If the uterus is not felt anteriorly, then place the 'vaginal' fingers posterior to the cervix as shown in Figure 3. A retroverted uterus is readily felt in the posterior fornix. In such cases, the cervix usually points forwards.
- vi) Continue the pelvic examination to determine the size, shape, consistency and mobility of the uterus. Special care should be taken in case of retroverted uterus while determining the mobility.
- Refer to a specialist if the uterus is enlarged, irregular, soft or not mobile as it may be due to pregnancy or some pathology.



Figure 2: Palpation of an anteverted uterus



Figure 3: Palpation of a retroverted uterus

- vii) Feel the adenexa for ovary and fallopian tube as follows. Move the 'abdominal' fingers to one side of the uterus and both the 'vaginal' fingers to the lateral fornix on the same side (see Figure 4). Press the adenexa towards the 'vaginal' fingers and with the vaginal fingers gently feel for the ovary and the tube along the side of the uterus. Repeat the same on the other side.
- Refer to a specialist if there is any tenderness or mass in the adenexa as it is indicative of PID.



Figure 4: Palpation of the adenexa

- viii) Put the speculum and the anterior wall retractor (if used) in 0.5% bleach solution for 10 minutes.
- Wash the gloved hands and remove the gloves and put into 0.5% bleach solution for 10 minutes. Wash hands.
- x) Give instructions to rinse the gloves and instruments and sterilise.

Annexure 5

COC Screening and Follow-up Card

Name of Health Centre:

District:

State:

Registration number:

Name of the client:

Age:

Address:

Menstrual history

Age at menarche:

Date of last menstrual period.

Menstrual cycle: regular/irregular Flow. Scanty/moderate/heavy

Duration:

days

Pain:

Obstetrical history

Total number of pregnancies. Total number of living children. female male

Number of abortions: Induced

Spontaneous:

Date of last delivery/C-section/abortion.

History of jaundice during pregnancy:

History of ectopic pregnancy.

History of puerperal infection after delivery or abortion:

Breast feeding

Currently breast feeding:

Duration:

Gynaecological history

Inter-menstrual bleeding,

Post-coital bleeding.

History of cancer of the cervix or uterus:

History of pelvic tuberculosis.

History of RTIs/STDs/HIV

Discharge per vagina. Colour of discharge:

Itching: Ulcers of the genitalia. Swelling of the genitalia or groin:

Lower abdominal pain: Abdominal mass:

Medical history

History of smoking: (mention number of cigarettes or bidis)

History of stroke/ severe pain in calf muscle (deep vein thrombosis)/pulmonary

embolism

History of breathlessness/heart disease:

History of hypertension:

History of severe headache/ migraine

History of jaundice (specifically ask about jaundice during pregnancy)

History of liver disease or gall bladder disease:

History of diabetes: Years since diagnosed: Complications:

History of chronic cough/tuberculosis: On treatment:

History of epilepsy: On treatment:

History of lumps in the breast or cancer:

General and systemic examination

Weight: Pulse: BP: Presence of anaemia:

Signs of jaundice:

Breast: Lumps/ulcer

Heart:

Abdomen: Liver palpable: Any mass: Any tenderness:

Pelvic examination

External genitalia: Normal

Abnormal discharge/redness/patches/ulcer/growth/warts/ swelling

Per speculum examination: Normal

Discharge/bleeding/ulcer/growth

Bimanual examination

Cervix: Pointing backwards/ forwards Soft/firm/hard, tenderness on

movement/freely mobile, smooth/irregular surface, bleeds to touch

Uterus: Normal

Anteverted/retroverted

Normal/bulky/small, smooth/irregular surface, soft/firm, mobile/fixed

Adenexa: Normal

Tenderness, mass

Laboratory examination:

Haemoglobin: Urine sugar:

Vaginal smear:

Pap smear:

Details of COC administration

Type of COC prescribed:

Date of starting the COC:

Date advised for follow up:

Follow up

Date	Menstrual history	ВР	Pelvic examination	Remarks

Annexure 6

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